

Congress of the United States
Washington, DC 20515

March 11, 2020

Robert R. Redfield, M.D., Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

Dear Dr. Redfield,

We write to you today as a Democrat and a Republican who are coming together over deep shared concerns to urge you to authorize several new labs to test for the coronavirus. Simultaneously, we request the Food and Drug Administration (FDA) to validate and approve the use of automated (so called 'high throughput') technologies in New York laboratories. While the Centers for Disease Control and Prevention (CDC) and FDA have recently approved three New York labs for testing, six more major hospital labs are still needlessly waiting for approval. The only three labs in New York that you have approved are the Wasdworth lab, the NYC Public Health lab and the Northwell Health system. But the six additional New York labs that have applied to test are NewYork-Presbyterian, Memorial Sloan Kettering Cancer Center, the University of Rochester Medical Center, the State University of New York Upstate University Hospital, the Roswell Park Comprehensive Cancer Center, and Mount Sinai Hospital. These are all very sophisticated medical centers that are fully capable of doing this test and we urgently need to increase capacity for testing.

Further, validating and automated testing in New York will expand the testing capacity in one of the most affected regions of country. Right now, labs process each test individually. It is estimated that one of our labs can manually process about 80 tests a day right now but if they were authorized to use automated testing, they could dramatically increase capacity. This would allow us to meet and then eventually exceed Governor Cuomo's goal of completing 1,000 tests per day. We stand firmly in agreement with Governor Cuomo that we need to hit this goal very soon. While there is currently not a backlog of coronavirus tests in New York, we are very concerned that there will be one soon. While we are glad that the local hospitals in our district have test kits to gather samples, the tests still need to be run and a diagnosis determined at one of only a few locations in New York, adding valuable time to the process.

While you recently allowed a select few hospitals and labs to start developing their own coronavirus tests, this decision could have and should have been made weeks ago and could have included many more labs. We cannot afford any more delays in dramatically scaling our testing capabilities. According to the Associated Press, Germany has had more than 1,100 confirmed coronavirus cases, but just two deaths to date. Experts say rapid testing early on likely resulted in more diagnosing of the infected and gave the country a chance to contain and prepare for the virus. According to the publicly available data, our estimated current capacity for testing across the entire United States is just 7,800 tests per day. Prominent health experts are now stating that

their best estimate based on research is it will be eight weeks before we have all the nationwide testing we need.

Given the stakes, we expect immediate action from both the CDC and the FDA and we look forward to your prompt reply.

Sincerely,

A handwritten signature in blue ink, appearing to be 'MR', followed by a long horizontal line.

Max Rose
Member of Congress

A handwritten signature in blue ink, appearing to be 'TR', followed by a long horizontal line.

Tom Reed
Member of Congress